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CLAIMS

We claim:

1. A process for preparing modafinil comprising the steps of:
   a) oxidizing 2-[(diphenylmethyl)thio]acetamide with H_2O_2 in a mixture of a mineral acid with an alcohol or phase transfer catalyst,
   b) precipitating a solid containing modafinil from the mixture, and
   c) separating the mixture from the precipitated solid.
2. The process of claim 1 further comprising isolating modafinil in purity greater than or equal to 99.5% from the precipitated solid by a single crystallization.
3. The process of claim 2 wherein the modafinil is isolated in purity greater than or equal to 99.9% from the precipitated solid by a single recrystallization.
4. The process of claim 1 wherein the modafinil is isolated in pharmaceutically acceptable purity.
5. The process of claim 1 wherein the purity of the modafinil is measured by the relative area of peaks in a chromatogram obtained by ultraviolet detection using 225 nm wavelength light.
6. The process of claim 1 wherein the precipitated solid is modafinil in greater than or equal to 99 % purity.
7. The process of claim 6 wherein the precipitated solid is modafinil in greater than or equal to 99.5 % purity.
8. The process of claim 1 wherein the H_2O_2 is added to the mixture as a 10-50 weight percent solution in water.
9. The process of claim 1 wherein the mineral acid is selected from the group consisting of sulfuric acid, perchloric acid, and phosphoric acid.
10. The process of claim 1 wherein the alcohol is selected from the group consisting of isopropanol, *tert*-butanol, and 2-methyl-1-butanol.
11. The process of claim 1 wherein the mixture further includes an inert liquid organic medium.

12. The process of claim 11 wherein the inert liquid organic medium is selected from the group consisting of methanol, ethanol, ethylene glycol, acetone, dimethylcarbonate, and mixtures thereof.
13. The process of claim 11 wherein the oxidizing comprises suspending one equivalent of the 2-[(diphenylmethyl)thio]acetamide in an inert liquid organic medium in an amount of 0.07 to about 0.13 grams per milliter, adding from about 0.05 to about 0.2 molar equivalents of the mineral acid, from about 2 to about 4 equivalents of the alcohol and from about 1.5 to about 4 molar equivalents of H_2O_2 to the liquid organic medium.
14. The process of claim 13 wherein oxidizing further comprises heating the inert liquid organic medium.
15. Modafinil prepared by the process of claim 2.
16. Modafinil containing less than 0.02% 2-[(diphenylmethyl)sulfonyl] acetamide.
17. The modafinal of claim 16 essentially free of 2-[(diphenylmethyl)sulfonyl] acetamide.
18. The modafinil of claim 17 free of 2-[(diphenylmethyl)sulfonyl] acetamide.
19. Modafinil containing less than 0.02% 2-[(diphenylmethyl)sulfinyl] acetic acid.
20. Modafinil containing less than 0.02% methyl 2-[(diphenylmethyl)sulfinyl] acetate.
21. A process for preparing modafinil Form I comprising the steps of:
    a) dissolving modafinil in a liquid selected from the group consisting of acetone, acetonitrile, benzyl alcohol, dimethyl formamide, methanol, methyl ethyl ketone, pyrrolidone and mixtures thereof,
    b) crystallizing modafinil from the liquid, and
    c) separating the liquid to obtain modafinil Form I.
22. The process of claim 21 wherein the liquid is methanol or acetone.
23. A process for preparing modafinil Form I comprising the steps of:
    a) suspending modafinil in ethyl acetate for a period of time sufficient to convert it into modafinil Form I, and
    b) separating the ethyl acetate to obtain modafinil Form I.
24. A process for preparing modafinil Form I comprising the steps of:

a) suspending crystalline Form II modafinil in a liquid selected from the group consisting of methyl *t*-butyl ether, water, isobutyl acetate and mixtures thereof for a period of time sufficient to convert the Form II modafinil into modafinil Form I, and

b) separating the liquid to obtain modafinil Form I.

25. A process for preparing modafinil Form I by heating Form V modafinil to about 80°C or higher temperature for a period of time sufficient to convert the Form V modafinil into Form I modafinil.

26. A process for preparing modafinil Form I by heating Form VI modafinil to about 80°C or higher temperature for a period of time sufficient to convert the Form V modafinil into modafinil Form I.

27. A crystalline form of modafinil that produces a powder X-ray diffraction pattern with reflections at 14.3, 17.5, 20.5 and 21.3±0.2 degrees 2θ.

28. The crystalline modafinil of claim 27 denominated modafinil Form II.

29. The crystalline form of modafinil of claim 27 wherein the reflections at 14.3, 17.5, 20.5 and 21.3±0.2 degrees 2θ comprise a first set of reflections of strong intensity and wherein the crystalline form is further characterized by reflections of lesser intensity at 9.1, 10.3, 11.9, 15.2, 18.4, 24.6 and 26.6±0.2 degrees 2θ.

30. The crystalline form of modafinil of claim 27 that produces a powder X-ray diffraction pattern with reflections at 9.1, 10.3, 11.1, 11.9, 14.3, 15.2, 16.4, 17.5, 18.4, 20.5, 21.3, 24.6, 26.6±0.2 degrees 2θ.

31. A process for preparing the modafinil of claim 27 comprising the steps of:

a) suspending Form III modafinil in water for a period of time sufficient to convert Form III modafinil into the modafinil of claim 27, and

b) separating the water to obtain the modafinil of claim 27.

32. A process for preparing the modafinil of claim 27 comprising the steps of:

a) dissolving modafinil in a liquid selected from the group consisting of ethanol, isopropanol, *n*-butanol, *t*-butanol, methyl isobutyl ketone, ethylene glycol, dioxolane, dioxane and mixtures thereof,

b) crystallizing modafinil from the liquid, and

c) separating the liquid to obtain the modafinil of claim 27.

33. A crystalline form of modafinil that produces a powder X-ray diffraction pattern with reflections at 7.4, 10.5, 20.0 and 20.5±0.2 degrees 2θ.

34. The crystalline modafinil of claim 33 denominated modafinil Form III.

35. The crystalline form of modafinil of claim 33 wherein the reflections at 7.4, 10.5, 20.0 and 20.5±0.2 degrees 2θ comprise a first set of reflections of strong intensity and wherein the crystalline form is further characterized by reflections of lesser intensity at 9.0, 12.3, 22.1 and 24.5±0.2 degrees 2θ.

36. The crystalline form of modafinil of claim 35 that produces a powder X-ray diffraction pattern with reflections at 7.4, 9.0, 10.5, 12.3, 14.2, 14.7, 15.1, 16.4, 18.3, 20.0, 20.5, 21.1, 22.1, 24.5±0.2 degrees 2θ.

37. A process for preparing the modafinil of claim 33 comprising the steps of:

a) dissolving modafinil in a liquid selected from the group consisting of toluene and mixtures of ethanol and dimethylcarbonate,

b) crystallizing modafinil from the liquid, and

c) separating the liquid to obtain the modafinil of claim 33.

38. A crystalline form of modafinil that produces a powder X-ray diffraction pattern with reflections at 6.9, 10.4, 17.2, 20.3 and 22.7±0.2 degrees 2θ.

39. The crystalline modafinil of claim 38 denominated modafinil Form IV.

40. The crystalline form of modafinil of claim 38 wherein the reflections at 6.9, 10.4, 17.2, 20.3 and 22.7±0.2 degrees 2θ comprise a first set of reflections of strong intensity and wherein the crystalline form is further characterized by reflections of lesser intensity at 14.1, 18.5, 20.8, 21.6 and 25.0±0.2 degrees 2θ.

41. The crystalline form of modafinil of claim 40 that produces a powder X-ray diffraction pattern with reflections at 6.9, 10.4, 14.1, 17.2, 18.5, 20.3, 20.8, 21.6, 22.7, 25.0, 26.5, 27.6, 28.5±0.2 degrees 2θ.

42. A process for preparing the modafinil of claim 38 comprising the steps of:

a) dissolving modafinil in a liquid selected from the group consisting of tetrahydrofuran and dimethyl sulfoxide

b) crystallizing modafinil from the liquid, and

c) separating the liquid to obtain the modafinil of claim 38.

43. A crystalline hemisolvate of modafinil and dimethylcarbonate.

44. The crystalline hemisolvate of modafinil and dimethylcarbonate of claim 43 that produces a powder X-ray diffraction pattern with reflections at 9.3, 12.4, 18.2, 19.9 and 22.0±0.2 degrees 2θ.

45. The crystalline hemisolvate of modafinil and dimethylcarbonate of claim 43 denominated modafinil Form V.

46. The crystalline form of modafinil of claim 44 wherein the reflections at 9.3, 12.4, 18.2, 19.9 and 22.0±0.2 degrees 2θ comprise a first set of reflections of strong intensity and wherein the crystalline form is further characterized by reflections of lesser intensity at 7.4, 24.7, 26.2, 21.5, 23.6, 24.5 and 25.2±0.2 degrees 2θ.

47. The crystalline form of modafinil of claim 46 that produces a powder X-ray diffraction pattern with reflections at 7.4, 9.3, 10.5, 12.4, 14.7, 16.2, 18.2, 19.9, 21.5, 22.0, 23.6, 24.5, 25.2, 28.4, 29.5, 31.8±0.2 degrees 2θ.

48. A process for preparing the modafinil of claim 43 comprising the steps of:
    a) dissolving modafinil in liquid selected from the group consisting of methylcarbonate, ethanol and dimethylcarbonate mixtures, water and dimethylcarbonate mixtures and acetone and dimethylcarbonate mixtures
    b) crystallizing modafinil from the liquid, and
    c) separating the liquid to obtain the modafinil of claim 43.

49. A crystalline form of modafinil that produces a powder X-ray diffraction pattern with reflections at 9.3, 18.2, and 20.5±0.2 degrees 2θ.

50. The crystalline modafinil of claim 49 denominated modafinil Form VI.

51. The crystalline form of modafinil of claim 49 wherein the reflections at 9.3, 18.2, and 20.5±0.2 degrees 2θ comprise a first set of reflections of strong intensity and wherein the crystalline form is further characterized by reflections of lesser intensity at 9.0, 10.2, 12.4, 15.3, and 20.0±0.2 degrees 2θ.

52. The crystalline form of modafinil of claim 51 that produces a powder X-ray diffraction pattern with reflections at 9.0, 9.3, 10.2, 12.4, 14.2, 14.5, 15.3, 17.5, 18.1, 20.0, 20.5, 21.5, 22.0, 23.5, 24.5, 25.0±0.2 degrees 2θ.

53. A process for preparing the modafinil of claim 49 comprising the steps of:

a) suspending Form V modafinil in a liquid selected from the group consisting of water, ethanol and ethanol and water mixtures for a period of time sufficient to convert the Form V modafinil into the modafinil of claim 49, and

b) separating the liquid to obtain the modafinil of claim 49.

54. A pharmaceutical composition comprising the modafinil of claim 27 and a pharmaceutically acceptable excipient.

55. A pharmaceutical dosage form comprising the composition of claim 54.

56. A pharmaceutical composition comprising the modafinil of claim 33 and a pharmaceutically acceptable excipient.

57. A pharmaceutical dosage form comprising the composition of claim 56.

58. A pharmaceutical composition comprising the modafinil of claim 38 and a pharmaceutically acceptable excipient.

59. A pharmaceutical dosage form comprising the composition of claim 58.

60. A pharmaceutical composition comprising the modafinil of claim 49 and a pharmaceutically acceptable excipient.

61. A pharmaceutical dosage form comprising the composition of claim 60.